West Virginia University
Clinical Trials Research Unit

Protocol Design and Development Checklist

- ***General Protocol Questions***

- ❑ Does the protocol provide appropriate objectives and rationale?
- ❑ Does the study have scientific merit/clinical relevance? Is it a novel approach to treating a disease?
- ❑ Is the protocol ethical? Will the IRB have patient safety/ethics issues with it?
- ❑ Is the protocol in final form? Are all amendments included?
- ❑ Will the subjects benefit clinically from participating in the study?
- ❑ Are the endpoints appropriate for this study?
- ❑ Are there competing protocols?
- ❑ Are staging criteria clearly identified in those cases where staging is used?
- ❑ Does this study require a data safety monitoring (DSM) board? A DSM plan?
- ❑ Is the study unusually long in duration, i.e., could this impact drop-out rate?

- ***Study Population Questions***

- ❑ Do you have access to the study population as proposed?
- ❑ Are inclusion/exclusion criteria overly restrictive?
- ❑ Consider the likely screen failure ratio. Will sponsor pay for screen failures?
- ❑ Is the proposed enrollment goal realistic?
- ❑ Is the proposed enrollment period realistic?
- ❑ Will you need to recruit patients from external sources? If so, will sponsor provide funding?
- ❑ Are vulnerable populations involved, e.g., children or impaired adults with special consent issues?

- ***Ancillary Support (Pharmacy/Nursing/Laboratory/Radiology)***

- ❑ Does the protocol contain sufficient information regarding drug preparation and storage?
- ❑ Is the drug information regarding side effects and adverse effects clearly stated?
- ❑ Are drug or device storage/accountability requirements complicated?
- ❑ Will the drug be available for patients at the end of the study?
- ❑ Will coordination with other departments/services be required for study visits or procedures?
- ❑ Are procedures frequent; difficult; painful; inconvenient?
- ❑ Is the dosing schedule complex?
- ❑ Are qualified staff available?
- ❑ What are the inservice requirements?

- ❑ Is the workload realistic?
- ❑ How many study visits will be required by the sponsor?
- ❑ Who is expected to attend the Investigator's meeting?

- ***Biostatistics***

- ❑ Are the protocol objectives clearly and precisely stated?
- ❑ Are the endpoints clearly and precisely stated?
- ❑ Is a literature review or appropriate background information included?
- ❑ Is the subject population clearly defined, including inclusion and exclusion criteria?
- ❑ Are the criteria for evaluation and/or definition of endpoints clearly and precisely stated?
- ❑ Does the protocol include a description of the statistical analysis plan?
- ❑ Does the protocol include a clear description of the management and reporting of toxicities?
- ❑ For studies that are dose escalating and/or include maximal tolerated doses, are these clearly defined?
- ❑ When appropriate, are the early stopping rules clearly defined?
- ❑ When appropriate, are the descriptions of randomized methods, stratification, blinding clearly defined?

- ***Budget***

- ❑ Does sponsor's preliminary budget appear adequate?
- ❑ If sponsor contracts to pay for "evaluable" subjects, is the definition of an evaluable subject clear and acceptable?
- ❑ If the study is canceled prior to enrollment, will the sponsor pay for pre-study activities, e.g., IRB submission, meetings, chart reviews?
- ❑ Will sponsor pay for events that are difficult to budget in advance, such as:
  - Protocol amendments requiring consent form revisions?
  - Reconsenting subjects?
  - Unanticipated monitoring visits?
  - Audits?
  - Unexpectedly high number of SAEs?
- ❑ Will sponsor pay for an adequate number of screen failures?
- ❑ If necessary to store study records off-site, will sponsor provide support?

- ***Data Management***

- ❑ Are records storage facilities available? What are storage requirements?
- ❑ Will electronic or remote data retrieval systems be used? If so, will sponsor provide training?
- ❑ Are the case report forms (CRFs) complex? Multiple CRFs per subject?